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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/250,657	05/27/1994	PAUL J. MULHAUSER	B02217061	1585

7590

08/12/2003

JASON M HONEYMAN
WOLF GREENFIELD AND SACKS
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210

EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/250,657

Applicant(s)

MULHAUSER ET AL.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-64 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,60-64 and 73-76 is/are rejected.
- 7) ☒ Claim(s) 49-59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Interference No. 104,374 has been vacated. Upon review of the application and the procedures for invoking an interference, examiner believes that the claims of the application and the claims of the patent to Green, et al fail in meeting the requirements for establishment of an interference. *Ex parte* prosecution is resumed.

Currently, claims 46-64 and 73-76 are pending. Claims 1-45 and 65-72 have been cancelled.

Claim Rejections - 35 USC § 112

Claims 48,60,61,62,63,64,73-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as worded are incomplete. According to the specification, the loading and delivery apparatus (200) include main body (202), lumen (204), introducer shaft (206), stepped distal end (207) and cartridge (210). The preambles of claims 48, 75 and 76 define a "apparatus for loading and delivering" and "loading and delivering apparatus" however the body of the claims, as worded, fail to completely identify each element forming the loading and delivery apparatus. More specifically, the claims are devoid in positively claiming the cartridge. Nowhere in the specification is the loading and delivery apparatus configured and designed to perform without the cartridge. In fact, only one embodiment is disclosed in the specification and that embodiment is directed to the combination of the loading and delivery apparatus comprising the main

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body (202), lumen (204), introducer shaft (206), stepped distal end (207) and cartridge (210). The specification fails to disclose any other embodiments directed to an alternative means for loading the mesh to the inserter. The specification is specific to workings of the combination of the cartridge and the inserter tool. Therefore the claims as presented are incomplete.

Claims 49-59 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed May 5, 2003 have been fully considered but they are not persuasive. Applicant's argues that an identical set of claims and a nearly identical set of claims had been previously allowed. And due to history the claims have passed several examinations. This argument has no relevance in overcoming the outstanding rejections.

Applicant argues that the claims are definite in that they do particularity point out and distinctly claim the subject matter that Applicants regard as their invention. Moreover, applicant argues that one of ordinary skill in the art would readily understand the scope of the claims based on the description of a "loading and delivering apparatus" contained in the specification and the illustration of a "loading and delivering apparatus" provided in the drawings. Applicant argues that the specification and the drawings support the

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loading and delivery apparatus as broadly claimed. Applicant states that the "cartridge" is a feature of an embodiment of a loading and delivery apparatus. This statement is not clearly supported by applicant's disclosure. The specification discloses only one embodiment of the "loading and delivery apparatus" and not "an embodiment" of a plurality of embodiments. According to the specification, the loading and delivery apparatus (200) include main body (202), lumen (204), introducer shaft (206), stepped distal end (207) and cartridge (210). The specification fails to disclose any other embodiments directed to an alternative means for loading the mesh to the inserter. The specification is specific to workings of the combination of the cartridge and the inserter tool. Therefore the claims as presented are incomplete.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J Isabella whose telephone number is 703-308-3060. The examiner can normally be reached on Monday-Friday, 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on Monday-Friday.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

dji
August 9, 2003



David J. Isabella
Primary Examiner